Cancer Clinical Trials FAQ

What are Cancer Clinical Trials? – for Educating Insurance Companies

1. **Why do doctors conduct clinical trials on cancer patients?**
   Oncologists are trained and expected to enroll patients in clinical trials not only to advance treatment for the long term, but to provide the best possible care for their current patients. Clinical trials advance the treatment and potential for finding cures for illnesses that take a heavy toll on individuals, families, communities and public resources. When the trial yields a positive medical result, the cancer patient may live longer and continue to need expensive routine treatment. On the other hand, positive results may mean the patient no longer needs expensive, ongoing treatment. This makes calculating long-term cost benefits of successful, new treatments difficult.

2. **Don't clinical trials add to the cost of care for a patient, and therefore raise insurance premiums?**
   Clinical trials to not generally add to the cost of patient care. When a trial is added to the mixture of uncontrollable variables associated with routine cancer treatment, it is difficult, if not impossible, to determine whether the trial procedure is negatively impacting the cost of the overall treatment. Complications that arise may be a result of the trial, but they may not. Complications arise in many patients whether or not they are participating in a trial.

3. **What do the phases of clinical trials have to do with cost?**
   The phases of clinical research have nothing to do with cost, either to the investigator, to the patient, or to third parties. These phases are completely based on the science and financial implications of studies would have to be looked at on the basis of each individual study. All kinds of treatments can be included in any of the phases. Phases are ordered in the sequence that a new treatment is studied. Phase 2 and 3 trials are the most common in Montana. In phase 3 trials, the intervention drug would be covered by the drug company and the standard drug would need to be covered by the health plan. Phase 1 trials are usually for end stage patients who don't have any other options. Side effects are usually covered by the patient or payer. Medicare covers the costs of side effects at the 80% rate.

4. **Shouldn't the trial sponsor/drug company be covering the cost of the trial?**
   The sponsor of a clinical trial, usually the federal government or a pharmaceutical company, generally pays for the new treatment or device being tested. If the patient has primary coverage with Medicare, the Medicare plan covers routine care, like radiation and chemotherapy, during the clinical trial. Group health plans or health insurance issuers, however, often consider the entire treatment during the period of the trial to be "experimental or investigational" and determine it to have a potential negative impact on the cost of routine care.

5. **How do other states deal with cancer clinical trial coverage?**
   Since 1995, 34 states and Washington, D.C., have passed laws or implemented agreements requiring coverage for routine care for cancer patients. Following the example of the states,

Congress included a provision requiring such coverage under the Patient Protection and Affordable Care Act (ACA) in 2010. Medicare has required coverage since at least September 2000 and Medicare's National Coverage Decisions (NCD) was considered by the Council.

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Insurance 101 – for Educating Medical Providers

1. **Is there anywhere else for a patient to appeal an insurance denial other than the insurance company?**
   CSI can assist any patient who files a complaint alleging a plan's failure to pay a covered benefit whether or not a clinical trial is involved. Urgent pre-service appeals are available but not always understood by providers or participants. Assistance with the appeals process may allow for an expedited resolution based on the urgency of the requested treatment as reviewed by external medical reviewers.

2. **Why is routine care for a clinical trial so often denied by insurance companies?**
   Group health plans or health insurance issuers, however, often consider the entire treatment during the period of the trial to be "experimental or investigational" and determine it to have a potential negative impact on the cost of routine care. While coverage for cancer treatment is common in health plans, exclusions for "experimental or investigational" treatments are also common. A company's decision to deny a claim on that basis relies on their interpretation of "experimental or investigational," for which there is no uniform interpretation across issuers or plans.

3. **Is there any data on insurance company denials of cancer clinical trials?**
   No, many variables in the stressful situation a cancer patient is in prevent any comprehensive data from being collected. Anecdotal evidence suggests that the barriers encountered in accessing trials may occur much earlier than the formal appeals process. Initial conversations between parties that may not have access to full information may screen out some patients. There may not be complete understanding that the request is for "routine care" not for the "experimental care" that is the subject of the trial. Past denials by one payer in a particular situation may lead to patients or providers to make incorrect assumptions about future actions by the same or other payers.

4. **Is there a standard definition for routine care that all insurance companies could follow?**
   Many states and the federal government define "routine care" for cancer patients and require coverage of routine care for cancer patients. Those definitions generally say that routine care is the care a patient would get in the absence of a trial. Montana has never had a standard definition for routine care. The Cancer Clinical Trials Advisory Council, convened by Insurance Commissioner Monica Lindeen agreed on a standard definition and the commissioner recommended to the legislature that it be codified in Montana statute. Link here.

5. **What are the different types of insurance and how can they be compelled to cover routine care for patients?**
   Single employer self-funded plans are not regulated by CSI and (except for self-funded state government plans and MEWAS) cannot be compelled by state legislation. However, self-funded plans respond to market forces and educational efforts, and should be offered education and asked to begin or continue covering routine care for cancer patients in clinical trials according to the council's adopted definition for routine care. The coverage will be required for self-funded plans in federal law on January 1, 2014. ERISA is a very broad law from the 1970s that relates to many different employee benefits, including

pensions, but also relates to health plans that are employer sponsored. State insurance regulation does apply to fully-insured employer-sponsored health plans, but does not apply to self-funded employer-sponsored health plans, except for MEWA's (multiple employer welfare associations). ACA and HIPAA provisions apply to self-funded ERISA-regulated health plans, with some exceptions. Self-funded government plans are not regulated by ERISA or the CSI. There are specific sections state law dedicated to regulation of self-funded government plans, and many provisions of HIPAA and the ACA do apply to self-funded government health plans.

6. **Is a fear of "off label" trials causing complications leading to denials?**
   Some providers may engage in their own "off label trial" after reading about promising results in the literature. In these situations, insurers maybe accused of denial when the care is not part of an approved trial. (Lag between promising trial and FDA approval?)

7. **Do insurance companies deny coverage of trials because trials may require patients to go out-of-state, adding to costs?**
   It is rare, not common, that patients need to leave the State of Montana for care in clinical trials. This issue is not a part of NCI clinical trials and if it were a part of a drug trial, or a trial with an affiliated university, the cost of travel would be negotiated into the contract for that trial. Insurers commonly do not offer coverage for travel expenses for members traveling out of Montana for trial participation. Trial care can require the patient to relocate for periods of time, which is difficult financially and socially for patients and families. The cost of care varies widely across the United States and opening up coverage for trial care can lead to increased costs specifically due to increased charges outside the State of Montana. This is particularly important given the increased use of health savings account plans, in that members who receive care in states with high charges can be billed significant sums of money after insurance payment is made to the provider of care.